



4. The allegations in Paragraph 4 are Plaintiffs' characterizations of one or more publications, which speak for themselves, and require no response. To the extent that a response is deemed to be required, the allegations are denied.

5. The allegations in Paragraph 5 state legal conclusions and/or constitute Plaintiff's interpretations of the FDCA, to which no response is required. The remaining allegations in Paragraph 5 address regulatory actions taken by the FDA relating to mifepristone, to which no response is required. Other allegations in Paragraph 5 are Plaintiffs' characterizations of the document appended to the Complaint as Exhibit A, which speaks for itself, and requires no response. To the extent a response is deemed to be required, the allegations are denied.

6. The allegations in Paragraph 6 are Plaintiffs' characterizations of North Carolina law, including North Carolina Gen. Stat. § 14-44, 14-45, 14-45.1, 90-21.82, 90-21.90 and 10A NCAC subchapter 14E, to which no response is required. Defendant admits that certain provisions of North Carolina law, including the statutes cited above, pertain to the provision of abortion care in the State. Defendant avers that these statutes speak for themselves. The remaining allegations in Paragraph 6 constitute one or more conclusions of law, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

7. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 7, and therefore, denies the allegations in Paragraph 7.

8. Defendant admits that medical providers in North Carolina are subject to various state laws relating to the provision of abortion care, including state laws pertain to mifepristone. The remaining allegations in Paragraph 8 constitute one or more conclusions of law and/or

Plaintiffs' interpretations of state law, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

9. The allegations in Paragraph 9 constitute one or more legal conclusions and/or Plaintiffs' interpretations of state law, to which no response is required. To the extent that a response is required, the allegations in Paragraph 9 are denied.

10. The allegations in the first and fourth sentences of Paragraph 10 constitute one or more legal conclusions, to which no response is required. To the extent the allegations in the first and fourth sentences do not constitute legal conclusions, Defendant is without sufficient knowledge or information to admit or deny these allegations, and therefore they are denied. Defendant is without sufficient knowledge or information to admit or deny the allegations in the second sentence of Paragraph 10, and therefore, those allegations are denied. Defendant admits that medication abortion can present time-sensitive issues, and further admits that delays in the provision of abortion care can increase risks associated with such care. Except as admitted, Defendants deny the remaining allegations in Paragraph 10.

11. The allegations in Paragraph 11 state legal conclusions and/or constitute Plaintiff's interpretations of certain regulatory actions taken by the FDA relating to mifepristone, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

12. The allegations in Paragraph 12 state legal conclusions and/or constitute Plaintiff's interpretations of certain regulatory actions taken by the FDA relating to mifepristone, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

13. The statements in Paragraph 13 purport to characterize the Complaint and the nature of the case, to which no response is required. To the extent that a response is required, the allegations are denied.

**RESPONSE TO “PARTIES”**

14. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 14, and therefore, the allegations in Paragraph 14 are denied.

15. It is admitted that Joshua H. Stein is the Attorney General of North Carolina. It is admitted that AG Stein has been named as a defendant in this lawsuit in his official capacity. It is admitted that the Attorney General is the chief law enforcement officer in the State with power to enforce State law including certain provisions of the state laws addressed in the Complaint. Except as admitted, denied.

16. It is admitted that Jeff Nieman is the District Attorney for North Carolina’s 18th Prosecutorial District, that the District Attorney is responsible for criminal prosecutions under relevant North Carolina law occurring within Prosecutorial District 18, and that DA Nieman has been named as a defendant in this lawsuit in his official capacity. Except as admitted, denied.

17. It is admitted that Kody H. Kinsley is the Secretary of the North Carolina Department of Health and Human Services (NCDHHS). It is admitted that NCDHHS is charged with licensing of hospitals and certification of clinics that provide abortion; denial, suspension, and revocation of facility certifications; and investigations of complaints relating to clinics that provide abortion. Defendant further states that the statutes and rules speak for themselves and require no response. It is admitted that Secretary Kinsley has been named as a defendant in this lawsuit in his official capacity. Except as admitted, denied.

18. It is admitted that Michaux R. Kilpatrick, MD, PhD, is the President of the North Carolina Medical Board, an entity with regulatory authority relating to physicians in North Carolina. It is admitted that Dr. Kilpatrick has been named as a defendant in this lawsuit in her official capacity. The remaining allegations in Paragraph 18 purport to state one or more legal conclusions, to which no response is required.

19. It is admitted that Christine M. Khandelwal, DO, is a member and President-Elect of the North Carolina Medical Board, and further admitted that she has been named as a defendant in this lawsuit in her official capacity.

20. It is admitted that Devdutta G. Sangvai, MD, MBA, is a member and Secretary and Treasurer of the North Carolina Medical Board, and further admitted that he has been named as a defendant in this lawsuit in his official capacity.

21. It is admitted that John W. Rusher, MD, JD, is a member of the North Carolina Medical Board, and further admitted that he has been named as a defendant in this lawsuit in his official capacity.

22. It is admitted that William M. Brawley is a member of the North Carolina Medical Board, and further admitted that he has been named as a defendant in this lawsuit in his official capacity.

23. It is admitted that W. Howard Hall, MD, is a member of the North Carolina Medical Board, and further admitted that he has been named as a defendant in this lawsuit in his official capacity.

24. It is admitted that Sharona Y. Johnson, PhD, FNP-BC, is a member of the North Carolina Medical Board, and further admitted that she has been named as a defendant in this lawsuit in her official capacity.

25. It is admitted that Joshua D. Malcolm, JD, is a member of the North Carolina Medical Board, and further admitted that he has been named as a defendant in this lawsuit in his official capacity.

26. It is admitted that Miguel A. Pineiro, PA-C, MHPE, is a member of the North Carolina Medical Board, and further admitted that he has been named as a defendant in this lawsuit in his official capacity.

27. It is admitted that Melinda H. Privette, MD, JD, is a member of the North Carolina Medical Board, and further admitted that she has been named as a defendant in this lawsuit in her official capacity.

28. It is admitted that Anuradha Rao-Patel, MD, is a member of the North Carolina Medical Board, and further admitted that she has been named as a defendant in this lawsuit in her official capacity.

29. It is admitted that Robert Rich, Jr., MD, is a member of the North Carolina Medical Board, and further admitted that he has been named as a defendant in this lawsuit in his official capacity.

#### **RESPONSE TO “JURISDICTION AND VENUE”**

30. The allegations in Paragraph 30 state legal conclusions and/or constitute Plaintiff’s interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

31. The allegations in Paragraph 31 state legal conclusions and/or constitute Plaintiff's interpretations of law, to which no response is required. To the extent a response is deemed to be required, the allegations are denied. Defendant admits that NCDHHS is a state agency in North Carolina.

32. The allegations in Paragraph 32 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 32 pertaining to where Plaintiff is located and where Plaintiff practices medicine.

33. The allegations in Paragraph 33 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

34. The allegations in Paragraph 34 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied. To the extent the allegations in the third and fourth sentences of Paragraph 34 do not constitute legal conclusions, Defendant is without sufficient knowledge or information to admit or deny these allegations, and therefore they are denied. Defendant admits that physicians in North Carolina owe certain duties of care to their patients. Except as admitted, the allegations are denied.

35. The allegations in Paragraph 35 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is

deemed to be required, the allegations are denied. Defendants admit that the North Carolina laws being challenged in this case are currently in effect and enforceable. Except as admitted, denied.

**RESPONSE TO “FACTUAL ALLEGATIONS”**

36. The allegations in Paragraph 36 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

37. The allegations in Paragraph 37 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

38. The allegations in Paragraph 38 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

39. The allegations in Paragraph 39 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

40. The allegations in Paragraph 40 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

41. The allegations in Paragraph 41 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.



42. The allegations in Paragraph 42 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

43. The allegations in Paragraph 43 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

44. The allegations in Paragraph 44 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

45. The allegations in Paragraph 45 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

46. The allegations in Paragraph 46 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

47. The allegations in Paragraph 47 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. The allegations also purport to quote from an FDA guidance document, which speaks for itself, and to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

48. The allegations in Paragraph 48 state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. The allegations also purport to

quote from an FDA document, which speaks for itself, and to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

49. Defendant admits that mifepristone is used in medication abortion in a regimen with misoprostol. Defendant admits that typically patients first take mifepristone, which works by blocking the hormone progesterone, without which the pregnancy cannot continue, followed by misoprostol 24 to 48 hours later, which causes uterine contractions similar to an early miscarriage. Defendant admits that medication abortion typically involves cramping, pain, and bleeding, and further admits that more serious complications are rare. The third and fourth sentences of Paragraph 49 purport to quote from a medical journal, which speaks for itself, and to which no response is required. Except as admitted, denied.

50. Defendant admits that the FDA initially approved mifepristone in 2000 under the trade name Mifeprex for the medical termination of intrauterine pregnancy, in a regimen with misoprostol. The remaining allegations in Paragraph 50 purport to quote from a document, which speaks for itself, and to which no response is required. Except as admitted, denied.

51. Defendant admits that the FDA, since its initial approval in 2000, has made updates to the regulatory controls imposed on the drug. The allegations in Paragraph 51 purport to quote from a document, which speaks for itself, and to which no response is required. The last sentence of Paragraph 51 states legal conclusions and/or constitutes Plaintiff's interpretations of certain regulatory activity by FDA, to which no response is required. To the extent a response is deemed to be required, the allegations are denied. Except as admitted, denied.

52. The allegations in Paragraph 52 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain regulatory activity by FDA, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

53. The allegations in Paragraph 53 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA, and also purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

54. The allegations in Paragraph 54 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

55. The allegations in Paragraph 55 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA, to which no response is required. Certain allegations also purport to quote from one or more documents, which speak for themselves, and as to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

56. The allegations in Paragraph 56 purport to quote from a document, which speaks for itself, and as to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

57. The allegations in Paragraph 57 purport to purport to quote from a document and/or constitute Plaintiff's interpretations of certain regulatory activity by FDA, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

58. The allegations in Paragraph 58 purport to purport to characterize one or more documents and/or constitute Plaintiff's interpretations of certain regulatory activity by FDA, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

59. The allegations in Paragraph 59 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA, and also purport to quote from certain documents, to which no response is required.

60. Defendant admits that the FDA in June 2011 approved the first REMS for mifepristone under the statute. The remaining allegations in Paragraph 60 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA, and also purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

61. The allegations in Paragraph 61 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA, and also purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

62. Defendant admits that the FDA in 2016 approved changes to the mifepristone REMS. The remaining allegations in Paragraph 62 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

63. The allegations in Paragraph 63 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

64. The allegations in Paragraph 64 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

65. The allegations in Paragraph 65 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

66. The allegations in Paragraph 66 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

67. The allegations in Paragraph 67 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

68. The allegations in Paragraph 68 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport

to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

69. Defendant admits that the FDA in January 2023 approved a modification of the mifepristone REMS. The remaining allegations in Paragraph 69 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

70. The allegations in Paragraph 70 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

71. The allegations in Paragraph 71 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

72. The allegations in Paragraph 71 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

73. The allegations in Paragraph 73 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

74. The allegations in Paragraph 74 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain federal laws and/or regulatory activity by FDA and/or purport to quote from certain documents, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

75. The allegations in Paragraph 75 purport to quote from a document, which speaks for itself, and to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

76. Defendant admits that North Carolina law currently includes certain restrictions pertaining to the prescription and distribution of mifepristone in connection with abortion care services, and further admits that certain of these restrictions are not included in the FDA's REMS pertaining to mifepristone. The remaining allegations in Paragraph 76 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws and/or regulatory activity by FDA, to which no response is required. To the extent a response is deemed to be required, except as admitted, the allegations are denied.

77. Defendant admits that, in North Carolina, medication abortion is legal when performed in compliance with state law, including N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1, 90-21.82(1)(a). The remaining allegations in Paragraph 77 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

78. Defendant admits that North Carolina regulates the locations where abortion care services can take place. The remaining allegations in Paragraph 78 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is

required. To the extent a response is deemed to be required, except as admitted, the allegations are denied.

79. Defendant admits that North Carolina law currently includes certain requirements that must be satisfied before any abortion care services can be provided, including a medication abortion with mifepristone. The remaining allegations in Paragraph 79 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, except as admitted, the allegations are denied.

80. Defendant admits that North Carolina law currently includes certain restrictions pertaining to the provision of abortion care services, including potential criminal prosecution and/or civil action and/or administrative action. The remaining allegations in Paragraph 80 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, except as admitted, the allegations are denied

81. The allegations in Paragraph 81 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws and/or regulatory action by the FDA, to which no response is required. To the extent a response is deemed to be required, except as admitted, the allegations are denied.

#### **RESPONSE TO "CAUSE OF ACTION"**

82. Defendant incorporates by reference and specifically reasserts its responses to Plaintiff's allegations as set forth above.



83. The allegations in Paragraph 83 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

84. Defendant admits that North Carolina law currently includes certain restrictions pertaining to the provision of mifepristone in connection with abortion care services. The remaining allegations in Paragraph 84 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, except as admitted, the allegations are denied.

85. The allegations in Paragraph 85 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

86. The allegations in Paragraph 86 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

87. The allegations in Paragraph 87 purport to state legal conclusions and/or constitute Plaintiff's interpretations of certain laws, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

**RESPONSE TO “PRAYER FOR RELIEF”**

Paragraphs 1 through 4 in the “Prayer for Relief” constitute and/or characterize Plaintiff’s request for relief in this action, to which no response is required. To the extent a response is deemed to be required, the allegations are denied.

Except as expressly admitted above, Defendant denies each and every remaining allegation of the Complaint.

Respectfully submitted, this 22<sup>nd</sup> day of February, 2023.

/s/ Michael T. Wood

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